

NE In column 27, line 29, please delete "Isolation of" and insert in place thereof --B.
Isolation of--.

✓ In column 29, line 13, please delete "3'-GGAGTTCC-5'" and insert in place thereof
--3'-GGAGCTCC-5'--.

NE In column 31, line 19, please delete "110" and insert in place thereof --101--.
In column 32, line 50, please delete "pMMTAΔBPV" and insert in place thereof --
pMMTAΔBPV--.

NE In column 43, line 31, please delete "aspiratrr" and insert in place thereof --
aspirator--.

NE In column 45, line 63, please delete "whn" and insert in place thereof --when--.

IN THE CLAIMS:

Please delete claim 98 without prejudice or disclaimer.

REMARKS

Entry of the foregoing, and consideration of the instant application as well as
Applicants' renewed request for interference are respectfully requested.

Applicants note with appreciation the personal interview between Examiner
Moore and applicants' representatives. During the interview, the Examiner indicated that the
cancellation of claim 98 would place all pending claims in condition for allowance. The Examiner
further indicated that it would appear that the conditions have been met for an interference to be

declared, and finally that it would be his recommendation that all of the claims of the three Foster et al patents referred to below should be included in the interference.

Appendix A is attached hereto, indicating the status as of the date of this amendment of all patent claims, and of all added claims, in accordance with 37 C.F.R. §1.124(b)(2)(ii).

As requested by the Examiner, the changes made by the Certificate of Correction for U.S. Patent No. 4,775,624, which is being reissued by the instant application, have been incorporated into the instant application. The changes relate to non-substantive changes resulting from the Patent Office's errors in printing the Patent. No new matter is added by these amendments.

In addition, claim 98 has been deleted without prejudice or disclaimer. In view of the deletion of this claim, the rejection of claim 98 under 35 U.S.C. §112, second paragraph, is moot.

It is noted that claim 97 was rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification. It is the belief of the undersigned that this rejection was intended to apply instead to claim 98. The rejection refers to a DNA construct encoding an amino acid sequence that fuses the amino acid at position 199 to the amino acid at position 212. Such a construct is not recited in claim 97, but instead in claim 98, where the amino acid residues 200-211 of human protein C are removed in the DNA construct. Moreover, page 5 of the Official Action states that claims 93-97 raise no issues under 35 U.S.C. §112.

Page 6 of the Official Action states that claims 83-97 are allowed, and that canceling claim 98 and making the amendments found in the Certificate of Correction will place the instant application in condition for allowance. Since both of these are done by the instant amendment, it is respectfully believed that the application is now in condition for allowance. At this time, review of Applicants' renewed request for interference is appropriate.

Applicants' renewed request for interference is as follows:

I. IDENTIFICATION OF THE PATENTS

Applicants request that an interference be declared between the instant application and U.S. Patent Nos. 4,968,626, 5,073,609, and 5,302,529 to Foster et al ("the Foster '626 Patent," "the Foster '609 Patent," and "the Foster '529 Patent", respectively). Applicants' earlier requests for interference related only to the Foster '626 and '529 Patents. However, for the reasons set forth below, it is apparent that all three Foster Patents should be involved in the requested interference.

All three Foster Patents originate from a common original application for patent and share a common specification. The '609 and '529 Patents issued as voluntary divisional applications in which terminal disclaimers were filed to obtain their issuance. For both Patents, double patenting rejections were made that were not traversed. Hence, the claims of the '626 Patent, the '609 Patent, and the '529 Patent can be regarded as patentably indistinct from each other – they share a common specification, they are bundled together via terminal disclaimers, and they exist separately only because of prosecution decisions by Foster to divide the claims apart. As the CCPA noted in *In re Braithwaite*, 154 USPQ 29, 34 (CCPA 1967):

When a terminal disclaimer causes two patents to expire together a situation is created which is tantamount for all practical purposes to having all the claims in one patent.

Accordingly, in proposing a count and determining which claims should correspond to the proposed Count, the three Foster Patents have been treated as a single patent.

II. PRESENTATION OF PROPOSED COUNT

Attached Appendix B sets forth a proposed Count. The proposed Count is an alternative Count prepared after consideration of the subject matter claimed by the respective parties. As required by 37 C.F.R. §1.601(f) as recently amended, the proposed Count "defines the interfering subject matter between ... one or more applications and one or more patents."

The interfering subject matter between Bang et al ("Bang") and Foster et al ("Foster") relates to the human protein C gene, i.e., a DNA compound encoding human protein C. The proposed Count is directed to claim 1 of the instant application and claim 1 of the Foster '626 Patent, in the alternative. These are the broadest claims of the respective parties which recite a DNA compound encoding human protein C.

As described *supra*, the three Foster Patents identified in this Request are effectively a single patent. Accordingly, only a single representative claim from the Foster Patents is required for the Count. Claim 1 of the Foster '626 Patent is the appropriate claim because it is the broadest Foster claim relating to a DNA compound encoding human protein C.

Neither of the two claims of the Foster '609 Patent is an appropriate claim for the Count because these claims are directed merely to fragments of human protein C DNA (*i.e.*, DNA compounds consisting of the DNA that encodes only a part of the full DNA sequence needed to

encode the complete protein). Under *Amgen v. Chugai*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), neither claimed fragment represents the completed conception of the protein C gene. Hence, the "gene fragment" claims are not appropriate for determining priority of invention for the interfering subject matter (*i.e.*, the human protein C gene), and thus are not appropriate for use in an interference count.

Similarly, none of claims 1-4 of the Foster '529 Patent is an appropriate claim for the Foster portion of the proposed Count. These claims all relate to bacterial plasmids or bacteriophage transfer vectors comprising specific cDNA sequences, and, thus, are narrower than claim 1 of the '626 Patent.

In view of the above, only claim 1 of the Foster '626 Patent represents an appropriate claim to serve as Foster's portion of the Count.

III. IDENTIFICATION OF CLAIMS OF THE FOSTER PATENTS WHICH CORRESPOND TO THE PROPOSED COUNT

Claims 1-3 of the Foster '626 Patent, claims 1-2 of the Foster '609 Patent, and claims 1-4 of the Foster '529 Patent, *i.e.*, all of the Foster claims, should be designated as corresponding to the proposed Count.

Foster '626 Patent

Claims 1 and 3

Claim 1 of the Foster '626 Patent covers Foster's disclosed human DNA sequence. By reference to the specification, it can be seen that the cDNA sequence of human protein C, as

set forth in Figure 3 of the Foster '626 Patent, is a DNA sequence encoding a protein having human protein C biological activity. This claim corresponds exactly to one part of the proposed Count. Claim 3 of the Foster '626 Patent recites a bacterial plasmid or bacteriophage transfer vector comprising a cDNA sequence comprising the human protein C gene cDNA sequence. That cDNA sequence appears at Figure 3 of the Foster '626 Patent. Claim 3 of the Foster '626 Patent thus defines the same patentable invention as claim 1 of the Foster '626 Patent. Because of the use of the word "or," correspondence to at least one part of the proposed Count is sufficient.

Claim 2

Claim 2 of the Foster '626 Patent defines an "isolated DNA sequence comprising the sequence of FIG. 2, from bp 1 to bp 8972, which sequence codes for human protein C." Figure 2 of the Foster '626 Patent describes the complete genomic DNA sequence for human protein C. Since the genomic sequence codes for human protein C, it clearly falls within the scope of claim 1 of the '626 Patent which requires that the sequence "codes for a protein having substantially the same biological activity as human protein C." As such, claim 2 should also be designated as corresponding to the proposed Count.

Foster '609 Patent

Claims 1 and 2

Claim 1 of the Foster '609 Patent, directed to the DNA sequence encoding the heavy chain of human protein C, and claim 2 of the Foster '609 Patent, directed to a DNA

sequence encoding human protein C from amino acid 64 to amino acid 419 (i.e., a fragment of the human protein C cDNA sequence), correspond to at least one part of the proposed Count.

During prosecution of the application which became the Foster '609 Patent, the Examiner made an obviousness-type double patenting rejection of these two claims over the claims of the Foster '626 Patent, because "it would be obvious to select and isolate fragments of the cDNA and genomic clone disclosed in said patent." *See*, paragraph bridging pages 2-3 of the Official Action dated December 27, 1990, attached as Appendix C. This rejection was not disputed by Foster, but instead was acquiesced to by filing a terminal disclaimer. *See*, page 2 of Foster's Response dated April 29, 1991, attached as Appendix D. Foster thus admitted that claims 1 and 2 of the '609 Patent are obvious in view of claims directed to Foster's full-length human protein C cDNA sequence. Claims obvious from the Count are directed to the same patentable invention as the Count, and thus must correspond to the Count. 37 C.F.R. §1.601(n). These claims should, therefore, be so designated.

Foster '529 Patent

Claims 1-4

As explained above, claims 1-4 of the Foster '529 Patent all relate to bacterial plasmids or bacteriophage transfer vectors comprising specific cDNA sequences, and thus are narrower than, but within the scope of, claim 1 of the '626 Patent. Therefore, claims 1-4 of the Foster '529 Patent are directed to the same invention as the proposed Count and correspond to the proposed Count.

IV. CLAIMS OF THE BANG REISSUE APPLICATION WHICH CORRESPOND TO THE PROPOSED COUNT

All pending claims in the instant reissue application should be designated as corresponding to the proposed Count. The only difference between the present Request and the initial Request filed on August 9, 1999, is that instant claims 81 and 82 are requested to be designated as corresponding to the proposed Count for the same reasons that claims 1 and 2 of the Foster '609 Patent should be designated as corresponding to the Count.

VI. APPLICATION OF TERMS OF APPLICATION CLAIMS

No new claims are being added to the Bang reissue application by this Request. A showing of the patentability of newly added claims thus is not required.

VII. EXPLANATION OF HOW THE REQUIREMENT OF 35 U.S.C. §135(b) IS MET

According to 35 U.S.C. §135(b), "[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted."

In the instant case, it is clear that the requirement of §135(b) is met. Bang Patent claims 1-82 all issued long before any of the Foster Patent claims. Claims 1-82 of the Bang Patent issued in U.S. Patent No. 4,775,624 on October 4, 1988, i.e., prior to the issuance of any of the Foster Patents. The Foster '626 Patent issued November 6, 1990, the Foster '609 Patent issued December 17, 1991, and the Foster '529 Patent issued April 12, 1994. Moreover, at the very

least, Bang claim 1 as issued was originally presented as claim 1 in Application Serial No. 699,967, filed on February 8, 1985. Claims 1-82 of the Bang reissue application were thus present in the Bang Patent and as recited therein are "the same as, or for the same or substantially the same subject matter as, a claim of" the issued Foster Patents, and were present prior to one year from the dates on which the Foster '626 Patent, the Foster '609 Patent, and the Foster '529 Patent issued.

Further, during prosecution of the Foster '626 Patent, the pending claims were rejected under 35 U.S.C. §102(e) and §103 over the Bang '624 Patent, which is being reissued by the instant application. *See*, pages 4-5 of the Official Action dated June 2, 1989, in the prosecution of the application which matured into the Foster '626 Patent, attached as Appendix E. The cloning and expression methods and compositions of Bang were said by the Examiner to anticipate the Foster claims. Since Foster was attempting to claim the same invention as already issued in the Bang Patent, the only way Foster should have been allowed to respond to the rejection would have been to file appropriate declarations pursuant to 37 C.F.R. §1.608(b) to provoke an interference.

"When the reference in question is a noncommonly owned patent claiming the same invention as applicant and its issue date is less than 1 year prior to the filing date of the application being examined, applicant's remedy, if any, must be by way of 37 C.F.R. § 1.608 instead of 37 C.F.R. § 1.131." MPEP §715.05. Nevertheless, the Examiner improperly withdrew the rejection over the Bang Patent in response to a Declaration by Foster under 37 C.F.R. §1.131. Had Foster's improper §131 Declaration been refused, as it should have been, and Foster been

forced to file one or more §1.608(b) Declarations, then the interference would have occurred prior to issuance of any of the Foster patents. This alone should be enough to satisfy §135(b).

VIII. EXPLANATION OF WHY AN INTERFERENCE SHOULD BE DECLARED

As stated in 37 C.F.R. §1.601(i), "[a]n *interference* is a proceeding instituted in the Patent and Trademark Office before the Board to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention" [emphasis in original]. According to 37 C.F.R. §1.601(n), "[i]nvention A is the *same patentable invention* as an invention 'B' when invention 'A' is the same as (35 U.S.C. §102) or is obvious (35 U.S.C. §103) in view of invention 'B' assuming invention 'B' is prior art with respect to invention 'A'" [emphasis in original].

Claims 1-97 of the instant Bang application define the same patentable invention as claims 1-3 of the Foster '626 Patent, claims 1-2 of the Foster '609 Patent, and claims 1-4 of the Foster '529 Patent. All of the claims of these three Foster Patents, and all of the claims of the instant application, are directed to embodiments which recite a sequence encoding human protein C polypeptide, or embodiments which are anticipated by or obvious in view of such a sequence. By comparing the sequences disclosed in the instant application to those in the Foster '626 Patent, the Foster '609 Patent and the Foster '529 Patent, it can be seen that the sequences are substantially the same.

The prosecution histories of the Foster '626 Patent, Foster '609 Patent, and the Foster '529 Patent also show that these three patents are claiming the same invention as Bang in the instant application. As discussed above, to obtain allowance, the Foster '529 Patent and the

Foster '609 Patent were terminally disclaimed over the Foster '626 Patent to overcome obviousness-type double patenting rejections. *See*, paragraph bridging pages 2-3 of the Official Action dated December 27, 1990, attached as Appendix C. As also discussed above, during prosecution of the Foster '626 Patent, the pending claims were rejected under 35 U.S.C. §102(e) and §103 over the Bang '624 Patent, which is being reissued by the instant application. *See*, pages 4-5 of the Official Action dated June 2, 1989, attached as Appendix E.

Because the claims of the Bang application and the Foster Patents all define the same patentable invention, an interference should be declared between claims 1-97 of the instant Bang application, claims 1-3 of the Foster '626 Patent, claims 1-2 of the Foster '609 Patent, and claims 1-4 of the Foster '529 Patent.

IX. CONCLUSION

Applicants respectfully request that an interference be declared employing the proposed Count set forth on attached Appendix B with claims 1-97 of the instant Bang application, claims 1-3 of the Foster '626 Patent, claims 1-2 of the Foster '609 Patent, and claims 1-4 of the Foster '529 Patent designated as corresponding to the Count. Such action is respectfully requested.

Further and favorable action in the above-identified application by indicating that all pending claims are in condition for allowance, and taking the necessary action to have an interference declared, is respectfully requested. In the event that there are any questions relating to this paper, it would be appreciated if the Examiner would contact the undersigned attorney so that prosecution is expedited.

Respectfully submitted,

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Date: January 11, 2001

APPENDIX A

<u>CLAIM</u>	<u>STATUS</u>
1	Pending in original form.
2	Pending in original form.
3	Pending in original form.
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97	Pending in original form.
98	Deleted.

APPENDIX B

PROPOSED COUNT

A constructed DNA compound that comprises double-stranded deoxyribonucleic acid that encodes a polypeptide with human protein C activity, wherein the coding strand is:

5'-R1_N-R_M-GCC AAC TCC TTC CTG GAG GAG CTC CGT CAC AGC
AGC CTG GAG CGG GAG TGC ATA GAG GAG ATC TGT GAC TTC GAG
GAG GCC AAG GAA ATT TTC CAA AAT GTG GAT GAC ACA CTG GCC
TTC TGG TCC AAG CAC GTC GAC GGT GAC CAG TGC TTG GTC TTG
CCC TTG GAG CAC CCG TGC GCC AGC CTG TGC TGC GGG CAC GGC
ACG TGC ATC GAC GGC ATC GGC AGC TTC AGC TGC GAC TGC CGC
AGC GGC TGG GAG GGC CGC TTC TGC CAG CGC GAG GTG AGC TTC
CTC AAT TGC TCG CTG GAC AAC GGC GGC TGC ACG CAT TAC TGC
CTA GAG GAG GTG GGC TGG CGG CGC TGT AGC TGT GCG CCT GGC
TAC AAG CTG GGG GAC GAC CTC CTG CAG TGT CAC CCC GCA GTG
AAG TTC CCT TGT GGG AGG CCC TGG AAG CGG ATG GAG AAG AAG
CGC AGT CAC CTG AAA CGA GAC ACA GAA GAC CAA GAA GAC CAA
GTA GAT CCG CGG CTC ATT GAT GGG AAG ATG ACC AGG CGG GGA
GAC AGC CCC TGG CAG GTG GTC CTG CTG GAC TCA AAG AAG AAG
CTG GCC TGC GGG GCA GTG CTC ATC CAC CCC TCC TGG GTG CTG
ACA GCG GCC CAC TGC ATG GAT GAG TCC AAG AAG CTC CTT GTC
AGG CTT GGA GAG TAT GAC CTG CGG CGC TGG GAG AAG TGG GAG
CTG GAC CTG GAC ATC AAG GAG GTC TTC GTC CAC CCC AAC TAC

AGC AAG AGC ACC ACC GAC AAT GAC ATC GCA CTG CTG CAC CTG
GCC CAG CCC GCC ACC CTC TCG CAG ACC ATA GTG CCC ATC TGC
CTC CCG GAC AGC GGC CTT GCA GAG CGC GAG CTC AAT CAG GCC
GGC CAG GAG ACC CTC GTG ACG GGC TGG GGC TAC CAC AGC AGC
CGA GAG AAG GAG GCC AAG AGA AAC CGC ACC TTC GTC CTC AAC
TTC ATC AAG ATT CCC GTG GTC CCG CAC AAT GAG TGC AGC GAG
GTC ATG AGC AAC ATG GTG TCT GAG AAC ATG CTG TGT GCG GGC
ATC CTC GGG GAC CGG CAG GAT GCC TGC GAG GGC GAC AGT GGG
GGG CCC ATG GTC GCC TCC TTC CAC GGC ACC TGG TTC CTG GTG
GGC CTG GTG AGC TGG GGT GAG GGC TGT GGG CTC CTT CAC AAC
TAC GGC GTT TAC ACC AAA GTC AGC CGC TAC CTC GAC TGG ATC
CAT GGG CAC ATC AGA GAC AAG GAA GCC CCC CAG AAG AGC TGG
GCA CCT TAG-3'

wherein

A is deoxyadenyl,

G is deoxyguanyl,

C is deoxycytidyl,

T is thymidyl,

R is 5'-GCC CAC CAG GTG CTG CGG ATC CGC AAA CGT-3'

or 5'-CAC CAG GTG CTG CGG ATC CGC AAA CGT-3'

R¹ is

5'-ATG TGG CAG CTC ACA AGC CTC CTG CTG TTC GTG

GCC ACC TGG GGA ATT TCC GGC ACA CCA GCT CCT

CTT GAC TCA GTG TTC TCC AGC AGC GAG CGT-3'

or 5'-ATG TGG CAG CTC ACA AGC CTC CTG CTG TTC GTG

GCC ACC TGG GGA ATT TCC GGC ACA CCA GCT CCT

CTT GAC TCA GTG TTC TCC AGC AGC GAG CGT GCC-3'

M is 0 or 1, and

N is 0 or 1,

provided that when M is 0, N must necessarily also be 0 and that when

R is 5'-GCC CAC CAG GTG CTG CGG ATC CGC AAA CGT-3',

R¹ must necessarily be

5'-ATG TGG CAG CTC ACA AGC CTC CTG CTG TTC GTG

GCC ACC TGG GGA ATT TCC GGC ACA CCA GCT CCT

CTT GAC TCA GTG TTC TCC AGC AGC GAG CGT-3';

and that when

R is 5'-CAC CAG GTG CTG CGG ATC CGC AAA CGT-3',

R¹ must necessarily be

5'-ATG TGG CAG CTC ACA AGC CTC CTG CTG TTC GTG

GCC ACC TGG GGA ATT TCC GGC ACA CCA GCT CCT

CTT GAC TCA GTG TTC TCC AGC AGC GAG CGT GCC-3';

or

An isolated human DNA sequence which codes for a protein having substantially the same biological activity as human protein C.